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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,654	03/20/2001	Gilbert V. Levin	41272	9978

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EXAMINER
OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/01/2002 3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,654	LEVIN, GILBERT V.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Abstract Objected to: Minor Informalities

The Abstract of the Disclosure is objected to because of the bracketed number preceding the first line of the abstract. Appropriate correction is required. See M.P.E.P. § 608.01(b).

Claim rejections – 35 U.S.C. 112(1)

> The following is a quotation of the first paragraph of 35 U.S.C. § 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim is drawn to a method for promoting cardiovascular health in a mammal in need of such treatment comprising administering to said mammal an efficacious amount of tagatose, dosage of 50 to 1,500 mg/kg to raise the HDL level in the mammal; wherein the tagatose is D-tagatose, L-tagatose, or a mixture of the two isomers.

The written discription requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by relevant identifying or functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to show the applicant was in possession of the claimed genus. If the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlative. In the instant specification, the genus is that of tagatose. Applicant claims to be in possession of a method employing species of this genus, specifically L-tagatose or a mixture of the two in promoting cardiovascular health via elevation of HDL. Applicant's specification is based on a study using D-tagatose, exclusively for the elevation of HDL. There is no actual reduction to practice, support in the specification, nor nexus in the state of the art for the use of L-tagatose or a mixture of D and L-tagatose to promote cardiovascular health via elevation of HDL levels in a mammal. The lone example presented on p. 2 of the specification seems to present a hypothetical treatment scenario that does not clearly lend support to whether applicant was in possession of the administration of L-tagatose or a mixture of the two isomers for a method of promoting cardiovascular health.

Claim Rejections - 35 U.S.C. 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zehner et al., U.S. Patent No. 5,356,879.

Claims 1-5 are drawn to a method for promoting cardiovascular health in a mammal in need of such treatment comprising administering to said mammal an efficacious amount of tagatose, dosage of 50 to 1,500 mg/kg to raise the HDL level in the mammal.

Claim 6 is drawn to the method of claim 1 wherein the tagatose is combined with a medication known to be useful in promoting cardiovascular health.

Zehner anticipates claims 1-5 as it teaches the administration of D-tagatose to a mammal, using a dosage within the claimed range, specifically 1 g/kg body weight (col.2, lines 45-60) to lower the rate of glycosylation end products that accumulate with age, that may be responsible for conditions such as atherosclerosis, capillary angiopathy and heart disease (col.3, lines 21 – col. 4, line 33; and col.1, lines 40-47). Mammals who have atherosclerosis would clearly be populations that would be in need of increasing levels of HDL; thus, per *In re Nowitzki*, the administration of tagatose by Zehner to reduce the occurrence of complications such as atherosclerosis due to accumulated glycosylation end products inherently anticipates applicant's intended use for increasing HDL and would clearly promote cardiovascular health.

Zehner however does not teach the combination of D-tagatose with a medication known to be useful in promoting cardiovascular health; however, it is prima facie

obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose, *In re Kerkoven,* 626 F.2d 846, 205 USPQ 1069 (C.C.P.A. 1980).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine D-tagatose with an agent useful in promoting cardiovascular health in a method for increasing the levels of HDL in a mammal.

A person of ordinary skill in the art would have been motivated to combine D-tagatose with an agent useful in promoting cardiovascular health in a method for increasing the levels of HDL in a mammal given that the agents have been recognized in the prior art as being individually useful for conditions associated with low HDL levels.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.